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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,643	01/09/2006	Richard L. Arden	ARC-100-PCT-US	2298

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EXAMINER	
ALIKHANI, SHADI	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
07/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No.	Applicant(s)	
	10/511,643	ARDEN, RICHARD L.	
	Examiner	Art Unit	
	SHADI ALIKHANI	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/18/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 10/18/2004.

2. Claims 1-20 are currently pending and have been examined.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1-3, 6-7, 9-10, 13, 15-17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Clement et al. (US 5,203,769).

Claim 1:

Clement et al. as shown disclose the following limitations:

- *an elongated tubular structure, said tubular structure defining distal and proximal ends and a passageway between the ends,* (see Fig. 15 and 28)
- *the distal end portion being generally frusto-conically shaped and positionable within the canal or passage,* (see Fig. 15)
- *the frusto-conical end portion including an enveloping lip sized to envelop and be engaged by a foreign body drawn there within,* (see Fig. 15, #238 and 239) *and*
- *the proximal end being removably connectible to a source of negative pressure, a lowering of the pressure in the passageway operating to suction and captivate the foreign particle into the distal end,* (col. 7, ln 18-20 and ln 43-51; col. 6, ln 41-46) *and*

- *a valve in operable relation with the passageway for adjusting the amount of air that is drawn between the distal and proximal ends of the tubular structure* (co. 4, ln 54-57; col. 5, ln 14-19; col. 6, ln 5-14 and ln 47-49).

Claim 2:

Clement et al. disclose the above limitations as shown and additionally disclose:

- *said valve* (Fig. 2, #12) *includes an inlet* (30) *and an outlet* (32), *and said tubular structure includes first* (24) *and second* (26) *portions,*
- *said first portion including a rearward end* (Fig. 2, #30) *and said distal end* (Fig. 15, #239),
- *said rearward end being connectible to the inlet* (30) *of said valve, and said second* (26) *portion includes a forward end* (see Fig. 2) *and said proximal end* (see Fig. 1), *said forward end being connectible to the outlet (32) of said valve* (col. 7, ln 43-51).

Claim 3:

Clement et al. disclose the above limitations as shown and additionally disclose:

- *said first portion* (24) *is curvilinear* (see Fig. 15 and 28) *and the rearward and distal ends thereof are angularly offset and disposed at an angle θ relative to one another* (col. 2, ln 2-4).

Claims 6-7:

Clement et al. disclose the above limitations as shown and additionally disclose:

- *said valve includes a valve body* (Fig. 2, #12) *having said inlet* (30) *and outlet* (32),
- *a passageway* (see Fig. 2) *extending between said inlet and outlet and connecting the passages in said first* (24) *and second portions* (26), *and*

- *a valve stem having a passageway for varying the amount of flow permitted through the passageway of said valve body and passages of said tube structure* (col. 4, ln 49-60; col. 5, ln 14-19; col. 6, ln 5-10).
- *said valve stem is mounted for rotation relative to the valve body and positions the passageway thereof in the passageway of said valve body, wherein rotation of the stem causes the passageway in said stem to move into and out of register with the valve passageway and change the amount of air that is permitted to drawn into and through the tubular structure* (col. 4, ln 49-60; col. 5, ln 14-19; col. 6, ln 5-14).

Claim 9:

Clement et al. disclose the above limitations as shown and additionally disclose a tip (Fig. 28, #510) that is part of the conduit piece and thereby disclose *said enveloping lip is integrally formed with the distal end of the first portion* (co. 6, ln 24-29; col. 7, ln 3-14; col 2, ln 8-12).

Claim 10:

Clement et al. disclose the above limitations as shown and additionally disclose a tip (Fig. 28, #510) that is part of the conduit piece and polyethylene tubing (col. 7, ln 7), which is well known in the art to be a non-toxic and biocompatible material for utilization in medical or surgical instruments. Clement et al. thereby disclose *said enveloping lip* (Fig. 28, #510) *and first portion* (Fig. 2, #24 and Fig. 28, #500a) *are formed from a non-toxic material* (col. 7, ln 7), *said lip is of a flexible material, and said first portion is of a hard material* (col. 7, ln 3-14).

Claim 13:

Clement et al. disclose the above limitations as shown and additionally disclose:

- *a hollow generally cylindrical suction tube forming a suction passageway* (see Fig. 2, 15, and 28),

- *the suction tube having a distal end that is insertable within the cavity and forms an inlet to the passageway* (see Fig. 2, 15, and 28),
- *the distal end being frusto-conically shaped and adapted to be fitted in enclosing relation about the foreign object* (see Fig. 15, #238),
- *a proximal end* (Fig. 2) *that forms an outlet from the passageway and is connectible to a source of negative pressure whereby to draw the foreign body into the distal end of the suction tube* (col. 6, ln 41-46; col. 7, ln 18-20 and ln 43-51), *and*
- *a closure valve located in the passageway and movable between first and second positions to prevent and permit flow through the suction tube* (col. 4, ln 49-60; col. 5, ln 14-19; col. 6, ln 5-14).

Claim 15:

Clement et al. disclose the above limitations as shown and additionally disclose:

- *a forward end portion* (Fig. 15, #238) *of the suction tube is curvilinear, the proximal end* (Fig. 2, #26) *is connectible to the source of suction* (col. 6, ln 25-39 and 41-46; col. 7, ln 43-51), *and the closure valve* (12) *is integrally formed at the proximal end* (see Fig. 2, #26 and 16).

Claim 16:

Clement et al. disclose the above limitations as shown and additionally disclose:

- *said suction tube includes first* (Fig. 15, 238) *and second tube portions* (col. 6, ln 41-46; col. 7, ln 43-51),
- *the first portion being curvilinear* (238) *and the distal end thereof being insertable in the cavity,*
- *the second portion being axially extending and directly connectible to the source of suction* (col. 6, ln 41-46; col. 7, ln 43-51), *and the closure valve* (Fig. 15, #330) *being disposed between the first and second tube portions.*

Claim 17:

Clement et al. disclose the above limitations as shown and additionally disclose a tip (Fig. 28, #510) that is part of the conduit piece and polyethylene tubing (col. 7, ln 7), which is well known in the art to be a non-toxic and biocompatible material for utilization in medical or surgical instruments. Clement et al. thereby disclose *the distal end* (Fig. 15, #238 and Fig. 28, #520) *comprises an enveloping lip* (Fig. 28, #510) *of a flexible non-toxic material* (col. 7, ln 7), *and the tube is comprised of a generally rigid non-toxic material* (col. 7, ln 3-14).

Claim 19:

Clement et al. disclose the above limitations as shown and additionally disclose a tip (Fig. 28, #510) that is part of the conduit piece and thereby disclose *the lip is integrally formed with the distal end* (co. 6, ln 24-29; col. 7, ln 3-14; col 2, ln 8-12).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US 5,203,769).

Claim 4:

Clement et al. disclose the above limitations as shown, but do not explicitly disclose that *the angle θ is about 100° to about 150°.* It would have been obvious to one of ordinary skill in the art at the time of the invention to have the suction conduit curved down from an angle θ of about 100° to about 150°, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Claim 5:

Clement et al. disclose the above limitations as shown, but do not explicitly that *the angle θ is about 130° to about 140°.* It would have been obvious to one of ordinary skill in the art at the time of the invention to have the suction conduit curved down from an angle θ of about 130° to about 140°, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

8. Claims 8, 12, 14, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US 5,203,769) in view of Kieffer, III et al. (US 4,380,998).

Claim 8:

Clement et al. disclose the above limitations as shown, but do not explicitly disclose that *said enveloping lip is removably mounted to said distal end.* Kieffer, III et al. however, in Figures 1 and 2, item #40 disclose this limitation (col. 3, ln 20-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the removable soft tip speculum of Kieffer, because using a soft removable speculum with a nasally or auditorially insertable tube having a

hard body can protect the ear canal and by interchanging different tip sizes to fit different ear sizes helps to form a conforming seal to prevent air from leaking when suction is applied (Kieffer, col. 1, ln 24-25; col. 2, ln 5-13).

Claim12:

Clement et al. disclose the above limitations as shown, but do not explicitly disclose *a magnifying lens, the lens being affixed to the first portion to enable the user to see within the cavity and ensure that the lip envelops the foreign object.* Kieffer, III et al. however, in Figures 1 and 2, item #31 disclose this limitation (col. 3, ln 6-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the magnifying lens otoscope of Kieffer, because using a lens in conjunction with the suction tube would allow the device to be used as a diagnostic instrument (Kieffer, col. 3, ln 11) by providing a visual indication of the placement of tip with respect to the foreign object in the ear.

Claim 14:

Clement et al. disclose the above limitations as shown, but do not explicitly disclose *a magnifying lens, the lens being affixed to the suction tube to enable the user to see within the cavity and ensure that the distal end encloses the foreign object.* Kieffer, III et al. however, in Figures 1 and 2, item #31 disclose this limitation (col. 3, ln 6-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the magnifying lens otoscope of Kieffer, because using a lens in conjunction with the suction tube would allow the device to be used as a diagnostic instrument (Kieffer, col. 3, ln 11) by providing a visual indication of the placement of tip with respect to the foreign object in the ear.

Claim 18:

Clement et al. disclose the above limitations as shown, but do not explicitly disclose that *the lip is removably attached to the distal end.* Kieffer, III et al. however, in Figures 1 and 2, item #40 disclose this limitation (col. 3, ln 20-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the removable soft tip speculum of Kieffer, because using a soft removable speculum with a nasally or auditorially insertable tube having a hard body can protect the ear canal and by interchanging different tip sizes to fit different ear sizes helps to form a conforming seal to prevent air from leaking when suction is applied (Kieffer, col. 1, ln 24-25; col. 2, ln 5-13).

Claim 20:

Clement et al. disclose the above limitations as shown and additionally disclose:

- *a curvilinear first tube element* (Fig. 12, 14, 15, and 28),
- *the tube element being generally circular in cross-section and having a forward end, a rearward end, and a central body portion* (Fig. 2 and 12-15; col. 7, ln 43-51),
- *the forward end being frusto-conically shaped* (Fig. 15, #238) *and greater in diameter than the diameter of said central body-portion* (234);
- *the forward end portion forming an insertion tip* (Fig. 28, #510) *sized to envelop and capture a foreign object to be extracted from the ear canal or nasal cavity of a human, and*
- *the insertion end being angularly offset relative to the rearward end* (Fig. 12, 14, 15, and 28; col. 2, ln 2-4),

Clement et al. disclose the above limitations as shown and additionally disclose a tip (Fig. 28, #510) that is part of the conduit piece and polyethylene tubing (col. 7, ln 7), which is well known in the art to be a non-toxic and biocompatible material for utilization in medical or surgical instruments. Clement et al. thereby disclose *said insertion tip* (510) *and said tube element being*

formed from a non-toxic material, wherein said tip is of a flexible material and said tube element is of a rigid material (col. 7, ln 3-14).

Clement et al. disclose the above limitation as shown, and additionally disclose:

- *a second tube element* (Fig. 2, #26), *the element having a rearward end that is connectible to a source of suction and a forward end, means for controlling and varying the pressure and suction force produced in the tube elements* (col. 3, ln 47-49; col. 6, ln 5-14; col. 7, ln 43-51),
- *the means for controlling and varying being interposed between and connected to the rearward and forward ends, respectively, of the first and second tube elements* (col. 3, ln 47-49; col. 6, ln 5-14; col. 7, ln 43-51),

Clement et al. disclose the above limitations as shown, but do not explicitly disclose *a magnifying glass connected to the first tube element to enable a user to see within the cavity or canal and ensure that the insertion tip seats in enveloping relation about the foreign object.* Kieffer, III et al. however, in Figures 1 and 2, item #31 disclose this limitation (col. 3, ln 6-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the magnifying lens otoscope of Kieffer, because using a lens in conjunction with the suction tube would allow the device to be used as a diagnostic instrument (Kieffer, col. 3, ln 11) by providing a visual indication of the placement of tip with respect to the foreign object in the ear.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (US 5,203,769) in view of Kieffer, III et al. (US 4,380,998), further in view off Ehmsen et al. (US 5,377,668).

Claim 11:

Clement et al. disclose the above limitations as shown and additionally disclose *wherein said first portion includes a central body portion between said distal and rearward ends*, but do

not explicitly disclose *and the cross-section of said first portion expands, outwardly in extending in opposite axial directions from said central body portion towards said distal and proximal ends.* Kieffer, III et al. however, in Figures 1 and 2, item #40 disclose this limitation (col. 3, ln 20-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement with the frustoconical tip speculum of Kieffer, because using a tip with outwardly expanding towards the distal and proximal ends can allow the ear canal to be held in a dilated condition suitable for examination, which is also capable of conforming to the contour of the ear canal to provide a good pneumatic seal (Kieffer, col. 1, ln 21-23 and ln 61-64).

Clement et al. and Kieffer, III et al disclose the above limitations as shown, but do not explicitly disclose that *an exterior section of the second portion is provided with convolutions to enable easy and secure gripping.* Ehmesen et al. however in Figure 1, item #37 and #52 disclose this limitation (col. 8, ln 1-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the tubular suction device of Clement and the soft tip speculum of Kieffer with the convoluted handle of Ehmesen's medical device, because it would enhance comfort of use and relieve finger muscle tension during protracted procedural manipulation (Ehmsen, col. 8, ln 8-10).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHADI ALIKHANI whose telephone number is (571)270-5305. The examiner can normally be reached on Monday - Thursday 10AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached at (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shadi Alikhani 06/26/2008

/Shadi Alikhani/
Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/
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